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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/460,920	12/14/99	PIPER B	LA0046A

HM12/0117

023914
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EXAMINER	
COOK, R	
ART UNIT	**PAPER NUMBER**
1614	6

DATE MAILED: 01/17/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/460,920	Piper
Examiner	**Group Art Unit**
Rebecca Cook	1614

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-36* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-36* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *2 and 3*

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Claims 1-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1, 22-25 and others the intent of recitations "first line treatment" and "drug naive human patient" are not clear and the specification does not define the recitations

In claim 3, 21 and elsewhere the term "substantially" in the recitation "substantially equivalent efficacy" is relative.

It is not seen that claims 3 and 32-34 further limit claim 1. The specification discloses that the combination reduces side effects, therefore this is inherent in claim 1.

There is no antecedent basis in claim 1 for the recitations in claims 4 and 5 and 6 and 7 "starting daily dosage" and "daily maintenance dosage."

Claims 5 and 19 do not further limit claims 4 or 1. Claims 7 and 20 do not further limit claims 6 or claim 1. They require a "low dose" of metformin and glyburide.

In claims 14-16 the word "contains" is confusing as to what else the combination has.. Amending the claims to recite 'comprising" will overcome this rejection.

There is no antecedent basis in claim 1 for the recitation "metformin/glyburide dosage" of claims 17-18.

The abbreviation in claims 18 and 21, $HbA_{1c,}$ is confusing. The first time an abbreviation appears in a claim it must be in parentheses and be preceded by the full term.

In claims 18-20 the terms "where necessary' and "generally accepted medical practice" are confusing as to their parameters.

In claim 21 the recitation "characterized in that" is colloquial and confusing. Amending it to recite "wherein" will overcome this rejection. In claims 27 and 28 the term "such" is colloquial. Amending it to recite "so" will overcome this rejection.

In claim 25 the intent of the recitation "wherein the glyburide is such that the glyburide bioavailability is comparable to the glyburide bioavailability obtained with a separate administration of metformin and glyburide" is not clear.

In claim 29 should not "patients" be "particle size is."

In claim 30 the recitation "undersize value" is not clear and is not defined in the specification. It is not seen that it is an art recognized recitation.

There is no antecedent basis in claims 35 and 36 for the recitation "pharmaceutical formulation as defined in claim 1," since claim 1 is to a method of use.

In claim 36 the terms "and/or" is confusing. In re Anderegg 51 USPQ 66.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Press Release 9/30/99: Bristol-Myers Squibb Files NDA for Novel Oral Antidiabetic Drug (PR) in view of Earle et al.

PR discloses a method of using metformin and glyburide as initial therapy for patients with type 2 diabetes. The claims differ over PR in requiring a low dose combination. However, Earle et al disclose that it is known in the art to use low-dose glyburide plus metformin. It would therefore be obvious to one of ordinary skill in the art to use the low dose glyburide of Earle et al in the method of PR to yield the instant method, since PR discloses a method of using metformin and glyburide as initial therapy for patients with type 2 diabetes. One would be motivated by the desire to have a useful method to treat type 2 diabetes.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-36 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims [illegible]42-76 of copending Application No. 09/4[illegible]32,465. Although the conflicting claims are not identical, they are not

patentably distinct from each other because the method of '465 renders the instant method obvious.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-36 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 47-66 of copending Application No. 09/432,465. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

It is inherent that the side effects will be reduced using a lower dose combination.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (703) 308-4724. The examiner can normally be reached on Monday through Friday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Cintins, can be reached on (703) 38-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 3080-1235.

The foreign language references were considered to the extent of the English language abstract of structures.

Rebecca Cook

REBECCA COOK
PRIMARY EXAMINER
GROUP 1200

January 16, 2000